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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention

[60Day-13-0600]

Proposed Data Collections Submitted for
Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 or send comments to Ron Otten, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d)

ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

CDC Model Performance Evaluation Program (MPEP) for Mycobacterium tuberculosis and Nontuberculous Mycobacteria Drug Susceptibility Testing OMB # 0920-0600 (exp. 5/31/2013), - Revision - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

As part of the continuing effort to support domestic public health objectives for treatment of tuberculosis (TB), prevention of multi-drug resistance, and surveillance programs, CDC is requesting approval from the Office of Management and Budget to continue data collection from participants in the Model Performance Evaluation Program for Mycobacterium tuberculosis and Non-tuberculous Mycobacterium Drug Susceptibility Testing. This revision request includes (a) changing the title of the data collection to "CDC Model Performance Evaluation (MPEP) for Mycobacterium tuberculosis Drug Susceptibility Testing" to

reflect that nontuberculous mycobacteria are no longer included in the test package; (b) replacement of Laboratory Enrollment Form with a Participant Biosafety Compliance Letter of Agreement; (c) revision of the Pre-shipment Email; (d) addition of Instructions to Participants Letter; (e) revision of the MPEP M. tuberculosis Results Worksheet; (f) entering survey results online using a modified data collection instrument; (g) modification of Reminder Email; (h) modification of Reminder Telephone Script; and (i) modification of the Aggregate Report Letter.

While the overall number of cases of TB in the U.S. has decreased, rates still remain high among foreign-born persons, prisoners, homeless populations, and individuals infected with HIV in major metropolitan areas. To reach the goal of eliminating TB, the Model Performance Evaluation Program for Mycobacterium tuberculosis and Non- tuberculous Mycobacterium Drug Susceptibility Testing is used to monitor and evaluate performance and practices among national laboratories performing M. tuberculosis susceptibility testing. Participation in this program is one way laboratories can ensure high-quality laboratory testing, resulting in accurate and reliable testing results.

By providing an evaluation program to assess the ability of the laboratories to test for drug resistant M. tuberculosis strains,

laboratories also have a self-assessment tool to aid in optimizing their skills in susceptibility testing. The information obtained from the laboratories on susceptibility practices and procedures is used to establish variables related to good performance, assessing training needs, and aid with the development of practice standards.

Participants in this program include domestic clinical and public health laboratories. Data collection from laboratory participants occurs twice per year. The data collected in this program will include the susceptibility test results of primary and secondary drugs, drug concentrations, and test methods performed by laboratories on a set of performance evaluation (PE) samples. The PE samples are sent to participants twice a year. Participants also report demographic data such as laboratory type and the number of tests performed annually.

There is no cost to respondents to participate other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Domestic Laboratory	Participant Biosafety Compliance Letter of Agreement	93	2	5/60	16

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
	MPEP <i>Mycobacterium tuberculosis</i> Results Worksheet	93	2	30/60	93
	Online Survey Instrument	93	2	15/60	47
Total			0		156

DATE: January 14, 2013

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